Adhesives and FDA Approval

The FDA does not grant certification or approval of adhesives for use in the manufacturing of medical devices (see attached correspondence from FDA representative Charles Kyper). However, most medical device manufacturers that now use adhesives in the assembly of their devices usually do require the adhesives they select for evaluation to meet USP VI and/or ISO 10993 biomedical testing.

Since the user must submit his part for final testing and FDA certification, an adhesive's qualification to ISO 10993 or USP Class VI is viewed as sufficient to allow a user to determine "probable" device acceptance.

Adhesives are submitted as cured sheets of plastic for all biomedical tests. In the uncured state, all adhesives are toxic and hence must be properly cured to be acceptable for use in medical devices. It is therefore critical for processes to be defined with this criteria in mind and process controls established to assure adequate cure of adhesive bonds in the assembled device.

DYMAX®
Corporation
Adhesives and Adhesive Equipment

ISO 9001 Certified

March 18, 1992

Mr. Charles Kyper
Asst. to Director of Office
Of Device Evaluation
HF2-401
1390 Piccard Drive
Rockville, MD 20850

Dear Mr. Kyper:

Thank you for taking the time to discuss FDA "approval" regulations on adhesives for use in medical device assemblies. You confirmed that having a Master File with FDA in no way indicates FDA acceptance or approval of information contained therein or of the adhesive product associated with the information. To clarify, there is no "FDA" approval list of adhesives or coatings for medical device assembly.

To set the record straight with regard to the false claims of "FDA approval" being grated some adhesive and coating products, could you verify by signing below that the above is true with regard to FDA Masterfile definition.

Sincerely,

Laurie Gibbons
Adhesive Specialist

The above is consistent with our conversation and the FDA Masterfile definition.

Name Charles H. Kyper, Title Assistant to the Director – Reclassification and Compliance Office of Device Evaluation FDA Center for Devices and Radiological Health

Date March 26, 1992

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